



Talking Points on Appointing a Legally Authorized Representative

This document is designed to help researchers discuss Legally Authorized Representatives (LARs) with participants. We provide information about LARs and suggestions on how to broach the subject with participants, which can be a sensitive discussion topic.

In what situations should I ask a participant about appointing an LAR?

- **When concerns exist about their understanding and appreciation of consent information:** It is appropriate to ask a participant about appointing an LAR in situations where you are concerned that a participant lacks understanding or is unable to provide informed consent. Appointing an LAR is a simpler cognitive task than consenting to a complex trial, and most older adults support the use of LARs.¹⁻⁴
- **When the study involves multiple visits or the risk level is deemed high enough:** A major determinant of whether LARs are necessary is the risk level of the study. As the risk level increases, so too does the need to ensure participants have adequate understanding. It is also appropriate to ask all participants in studies that involve multiple visits—such as longitudinal studies—who they would appoint as an LAR. This is because the ability to provide informed consent could change during the course of the study.

How do I start a conversation about LARs?

- If understanding and appreciation of consent information is in question, you can begin by explaining:

“By law, we are not allowed to enroll someone in a study if we think they don’t understand the consent information. When this happens, we ask people if they have someone to help them make decisions. Given our discussion today, we have some concerns that you might not fully understand this study. Is there someone who could help you make a decision about participating in this study?”

- In cases where there are currently no concerns about understanding and appreciation of consent information, you can begin by saying:

“If you start having any problems understanding the study, would you want to prepare for that by choosing someone to be your Legally Authorized Representative? A Legally Authorized Representative is someone you appoint who would make research decisions for you when you are unable to. The person you choose would help you make a decision only if you could not make the decision about research yourself. It is a way of planning ahead in case something happens in future.”

[Note: Your state may have legislation that stipulates who can serve as an LAR. In some states, to be eligible to serve as an LAR, an individual may need to be appointed as a durable power of attorney for healthcare. Make sure to check with your IRB for guidance.]

What if I am worried the participant lacks the ability to appoint an LAR?

- The ability to appoint an LAR is a simpler cognitive task than consenting to a complex research study, as it involves making a decision that is based on existing relationships.¹ If the participant can provide the following information then they likely are able to appoint an LAR:
 - a) Name a specific and feasible person to serve as their LAR
 - b) Provide a reason for this choice when asked

How do I document the discussion?

- Check with your IRB. Your IRB may have a specific form for appointing an LAR.
- Check if your electronic data capture system(s) includes a mechanism to document discussions about LARs in the research record.
- If not, we have provided a sample note to file template that can be adapted to document the discussion. Your IRB should review the form before you use it.

References

1. Kim SY, Karlawish JH, Kim HM, Wall IF, Bozoki AC, Appelbaum PS. Preservation of the capacity to appoint a proxy decision maker: implications for dementia research. *Arch Gen Psychiatry*. 2011;68(2):214-220.
2. Kim SYH, Kim HM, McCallum C, Tariot PN. What do people at risk for Alzheimer disease think about surrogate consent for research? *Neurology*. 2005;65(9):1395-1401.
3. Kim SY, Kim HM, Langa KM, Karlawish JH, Knopman DS, Appelbaum PS. Surrogate Consent for Dementia Research: A National Survey of Older Americans. *Neurology*. 2009;72(2):149-155.
4. Kim SY, Karlawish JH, Kim HM, Wall IF, Bozoki AC, Appelbaum PS. Preservation of the capacity to appoint a proxy decision maker: implications for dementia research. *Archives of General Psychiatry*. 2011;68(2):214-220.